

CPA of Application No. 09/455,543
Attorney Docket No. 45112-045

a compound selected from a group consisting of forskolin, geldanamycin and okadaic acid,
said composition having a therapeutically effective amount of the compounds selected on a basis of a therapeutic treatment for soft tissue cancer.

REMARKS

Claims 2 and 17- 28 are cancelled without prejudice or disclaimer. Applicants respectfully reserve the right to file continuation applications. Claims 1, 5-14, and 16 are pending. Claim 1 is amended to encompass infringing subject matter. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned, "Version With Markings To Show Changes Made." No new matter has been added.

Election/Restriction

The Office Action states that claims 1-14 have been constructively elected by original presentation for prosecution on the merits and as such, Claims 17-28 are withdrawn from consideration as being directed to non-elected subject matter. Solely in an effort to advance prosecution, Applicants have cancelled withdrawn claims 17-28 without prejudice to, or disclaimer of, the subject matter contained therein or the right to file continuing applications therefor.

Double Patenting

Claims 1-2, 5-14 and 16 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-16 of copending Application No. 09/455,544. In response, Applicants respectfully acknowledge the need to cancel or amend claims if ultimately allowed claims in the above-captioned application improperly conflict with, or are coextensive in scope. Applicants respectfully reiterates its request that this rejection be held in abeyance until allowable subject matter is indicated.

Rejections Under 35 U.S.C. §112

Claims 1-2, 5-14 and 16 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly being non-enabled. Applicants respectfully traverse this rejection.

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As discussed previously, the test for whether a claimed invention is enabled pursuant to 35 U.S.C. § 112, first paragraph, is to determine whether one of skill in the art can make or use the claimed invention without undue experimentation in light of the application disclosure coupled with the information known in the art. *United States v. Telectronics, Inc.*, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988). Applicants are not required to explain every detail since they are speaking to those of ordinary skill in the art. *In re Howarth*, 210 U.S.P.Q. 690, 691 (CCPA 1981). Thus, a patent may be enabled even though some experimentation is necessary, as long as the amount of the experimentation is not unduly extensive. *Utter v. Hiraga*, 6 U.S.P.Q.2d 1709, 1714 (Fed. Cir. 1988).

Moreover, a rejection based on a lack of enablement cannot be maintained solely on the basis that the number of claimed compounds exceeds those specifically disclosed in the specification or that an inadequate number of specific examples is presented. There is no magical relationship between the number of representative examples and the breadth of the claims. In fact, **no working examples are necessary**, although the absence of examples could be a factor in determining undue experimentation. *In re Borkowski*, 164 U.S.P.Q. 642 (CCPA 1970). When a broad term is supported by the specification, an Applicant should not be denied the use of the term merely because it is broad. *In re Grier*, 144 U.S.P.Q. 654 (CCPA 1965). As explained by the Court of Customs and Patent Appeals:

Appellants have apparently not disclosed every catalyst which will work; they have apparently not disclosed every catalyst which will not work. The question, then, is whether in an unpredictable art, section 112 requires disclosure of a test with every species covered by a claim. To require such a complete disclosure would apparently necessitate a patent application or applications with "thousands" of examples or the disclosure of "thousands" of catalysts along with information as to whether each exhibits catalytic behavior resulting in the production of hydroperoxides. More importantly, such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. This would tend to discourage inventors from filing patent applications in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed.

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In re Angstadt, 190 U.S.P.Q. 214, 218 (CCPA 1976). In line with this statement, the Court of Customs and Patent Appeals in *In re Johnson and Farnham*, 194 U.S.P.Q. 187, 195 (CCPA 1977), citing *In re Goffe*, 191 U.S.P.Q. 429, 431 (CCPA 1976), exemplified:

[T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

Applicants respectfully reiterate the point that the asserted utility of the presently claimed invention is **not preventing or curing cancer**. Rather, the specification states that the presently claimed invention provides **therapy or treatment for cancer**, in particular, soft tissue cancers. Indeed, the examples in the specification exemplify preferred embodiments of the claimed invention. The specification specifically teaches that the claimed compositions are effective anticancer therapies that would readily be appreciated by those skilled in the art. Applicants have validated this presumption by conducting *in vitro* assays to measure the effects of the disclosed compositions.

Moreover, Applicants reiterate that the present specification is not a "hunting license", as inferred by the Office Action. If a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 U.S.C. § 112, is satisfied. *In re Brana*, 51 F.2d 1560, 1566, 34 U.S.P.Q.2d 1437, 1441 (Fed. Cir. 1993). *In re Johnson*, 282 F.2d 370, 373, 127 U.S.P.Q. 216, 219 (C.C.P.A. 1960); and *In re Hitchings*, 342 F.2d 80, 87, 144 U.S.P.Q. 637, 643 (C.C.P.A. 1965). Applicants respectfully submit that the present specification provides sufficient examples of preferred compositions that have been tested for therapeutic activity in several different kinds of *in vitro* assays, which are reasonably predictive of therapeutic activity. The exemplified assays, however, are not proof of safety, efficacy, toxicity, routes of administration and dosage of the recited compounds; the patent laws do not require them to be such indicators. Such issues are readily determinable in the art via routine, although possibly extensive, experimentation and are not probative in determining whether the claimed invention is enabled by the originally-filed specification. Indeed, such issues are addressed by other governmental agencies, e.g., the U.S. Food and Drug Administration, not the U.S. Patent and Trademark Office. In short, Applicants

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respectfully submit that the specification provides specific and useful teachings with enough detail to enable one of skill in the art to make and use the presently claimed invention. Thus, Applicants respectfully request reconsideration and withdrawal of the non-enablement rejection under 35 U.S.C. § 112, first paragraph.

CONCLUSION

If any issues remain outstanding or if an Examiner's amendment could be made to advance prosecution (e.g., an Examiner's Amendment), then Applicants respectfully invite the Examiner to contact the undersigned representative at the telephone number listed below.

Please grant any extensions of time deemed necessary for entry of this communication. Please charge any deficient fees, including Notice of Appeal fees, or credit any overpayment of fees, to Deposit Account No. 5000417.

Respectfully submitted,

Date: May 5, 2003

By: [Signature]
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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this document (including any paper referred to as being attached or enclosed) is being sent to the U.S. Patent and Trademark Office via facsimile transmission to (703) 872-9306 on the date indicated below, with a coversheet addressed to Commissioner for Patents, U.S. Patent and Trademark Office, Alexandria, Virginia 22213.

Date:

By:

May 5, 2003
[Signature]
Willem F. Gadiano, Registration No. 37,136

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ATTACHMENT
Version With Markings To Show Changes Made

IN THE CLAIMS

Claims 2 and 17-28 are cancelled, without prejudice to, or disclaimer of, the subject matter they contain.

Claim 1 is amended, as follows:

1. (Three Time Amended) A composition for the treatment of cancer, said composition comprising, in admixture with an acceptable carrier,

~~at least one~~ a compound selected from a group consisting of benzyl alcohol, cinnamic aldehyde, cinnamaldehyde, cinnamic alcohol, α -terpineol, carvacrol, citronellal, eugenol, iso-eugenol, thyme oil, thymol, and trans-anethole; and

~~at least one signal transduction modulator selected from a group consisting of cyclic adenosine monophosphate (cAMP), cAMP-dependent protein kinase, tyrosine kinase, calcium phospholipid-dependent protein kinase (PKC), mitogen-activated protein kinase family members, calcium-calmodulin-dependent protein kinase, and growth factor receptor inhibitors~~ a compound selected from a group consisting of forskolin, geldanamycin and okadaic acid,

said composition having a ~~pharmaceutically~~ therapeutically effective amount of the compounds selected on a basis of a therapeutic treatment for soft tissue cancer.